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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,296	06/21/2001	Thomas E. Tarara	0054.10	6348

21968 7590 06/19/2002

INHALE THERAPEUTIC SYSTEMS, INC  
150 INDUSTRIAL ROAD  
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EXAMINER

GOLLAMUDI, SHARMILA.S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/886,296

Applicant(s)

TARARA ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 4-15, 18-23 and 39-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-15, 18-23 and 39-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Amendment B and Election filed on March 13, 2002 is acknowledged.

Claims 4-15, 18-23 and 39-51 are included in the prosecution of this application.

#### ***Claim Objections***

Claims 4-15 and 18-23 are objected to because of the following informalities:

The instant claims depend on claim 39 and have improper dependency. Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 4-15, 39-47, 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (US 5855913, cited prior art) in combination with WO 94/04133 by themselves or in view of Yen (5308620, cited prior art).**

Hanes et al teach aerodynamically light particles for drug delivery to the pulmonary system. The particles have a tap density of less than 0.4 g/cm<sup>3</sup> and a diameter between 5 to 30 microns (Note abstract). Hanes teaches features such as irregular surface texture and porous structure contribute to low tap density and manipulation of these features permits the delivery of larger particle envelope volumes into the lungs (col. 9, lines 10-25). Further, low tap density particles are taught to have small aerodynamic diameter (instant diameter) (col. 9, lines 26-45). The particles

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contain surfactants such as DPPC and the microstructures are taught to encapsulate active agents, which allows the active to remain protected (col. 10, lines 37-50 and examples).

Hanes et al does not teach the use of calcium in the composition or instant pore size.

WO teaches dry powder composition for inhalation containing a drug and a carrier. The reference teaches the blending drugs with an excess of inert carrier which has a substantially larger than median particle size of the drug, the flow properties are enhanced and the dispensing accuracy are improved. WO teaches calcium carbonate as a common carrier material. (Note page 2)

Yen teaches the method of making stable, porous nanomatrixes. Yen teaches the advantages the porous nature of a carrier vesicle such as this structure allows the substrate of the biologically active molecules to diffuse into the interior of the nanomatrix and for the reaction products to diffuse out. The drugs can also diffuse out of the nanomatrix at rates dependent on the porosity of the nanomatrix carrier. (Note col. 8, lines 34-46).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use calcium carbonate in Hanes et al's dry powder composition since WO teaches calcium carbonate to be an inert carrier that enhances flow property and does not pose toxicity concerns.

The manipulation of tap density and pore size are deemed obvious to one of ordinary skill in the art since Hanes teaches the manipulation of surface roughness

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(porosity), diameter, and tap density determine the delivery site of the particles (col. 8, lines 19-68). Therefore, one would be motivated to manipulate the factors and fabricate the microstructure according to the region to be targeted. Further, motivation to manipulate the pore size is to control the rate of the release of actives from the carrier as taught by Yen; therefore depending on the drug used and the desired rate of release, one would be motivated to manipulate its size.

**Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hanes et al (US 5855913) in combination with WO 94/04133 in view of Igarashi et al (4201774).**

As set forth above, Hanes et al and WO teach dry powder inhaler compositions. Hanes teaches several active agents in the composition.

The references do not teach the specific use of aminoglycoside antibiotic.

Igarashi et al teaches aminoglycoside antibiotics for the treatment of gram-positive and gram-negative bacteria. Further, the reference teaches the use diluents such as calcium carbonate for the composition and the composition in a form of an inhalant (col. 5, lines 19-40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the instant medicament in Hanes et al's composition. One would be motivated to do so since the instant antibiotics treat gram-positive and gram-negative bacteria.

#### **Miscellaneous**

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The office has received the filing of the IDS and the initialed copy will be sent as soon as the examiner locates and reviews the IDS.

**Conclusion**

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

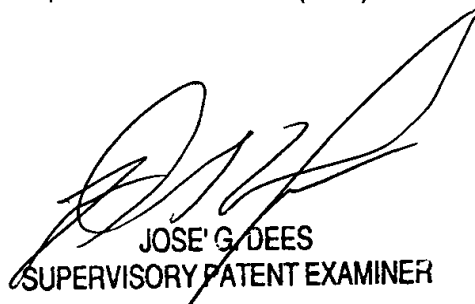
If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

SSG



June 12, 2002



JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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